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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/567,386

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Nikolaos Berntenis

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HOFFMANN-LA ROCHE INC.
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EXAMINER

EWOLDT, GERALD R

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/567,386	Applicant(s) BERNTENIS ET AL.	
	Examiner G. R. Ewoldt, Ph.D.	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17, 18, 23, 25 and 31 is/are pending in the application.
- 4a) Of the above claim(s) 3-13, 15, 17, 18, 23, 25 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/19/06</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Sequence Notice to Comply</u> . |

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DETAILED ACTION

1. Applicant's election of Group I, the peptide of SEQ ID NO:49, with traverse, submitted 7/07/10, is acknowledged.

Applicant cites MPEP chapter 800 and argues a lack of burden in the search of all of the Groups.

Applicant is advised that MPEP chapter 800 does not apply to the instant National Stage Application filed under 35 USC 371. MPEP chapter 1800 applies to the instant application and Lack of Unity has been properly established there under.

Applicant further argues that the cited reference, WO 93/18153 teaches only a sequence that is "apparently similar", "but not identical to", the sequence of SEQ ID NO:109.

Applicant has provided no evidence that the cited sequence in WO 93/18153 does not comprise that of SEQ ID NO:109 in the instant application, and it is further noted that Applicant did not traverse this finding in response to the International Preliminary Report on Patentability.

Also note that even under the rules of MPEP chapter 1800 multiple products, e.g., different unrelated peptides, are not considered to comprise a single invention.

It is noted that the elected invention, a peptide comprising the amino acid sequence of SEQ ID NO:49, is a fragment of the protein gamma-interferon-inducible lysosomal thiol reductase (GILT). Applicant is advised that peptides claimed in this application that consist of additional fragments of GILT will be considered to be non-elected species rather than separate inventions. Applicant is requested to identify any such fragments should they exist.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 3-13, 15, 17, 23, 25, and 31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected inventions/species. Note that Applicant incorrectly identified Claim 23 as reading on the elected invention.

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Claims 1, 2, and 14 are being acted upon.

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. All sequences in the specification and figures must be identified by SEQ ID NO:. See, for example, the sequences at pages 9, 39, 41, 42, etc. of the specification.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as anticipated by Arunachalam et al. (2000).

Arunachalam et al. teaches a peptide comprising the amino acid sequence of SEQ ID NO:49 (see particularly Figure 1A.).

The reference clearly anticipates the claimed invention.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Arunachalam et al. (2000) in view of Jüsten et al. (2000) and Godkins et al. (2001).

Arunachalam et al. has been discussed above.

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The reference teaching differs from the claimed invention only in that it does not teach a peptide comprising the amino acid sequence of SEQ ID NO:49 further comprising an MHC Class II molecule.

Jüsten et al. (2000) teaches that in their search for genes and gene products that might be involved in the pathogenesis of rheumatoid arthritis (RA) they found that GILT was overexpressed in RA patients (see particularly, page 167, column 2) and noted that "it is striking" that GILT colocalizes in APCs with intracellular MHC Class II molecules (see particularly, page 170, column 1).

Godkins et al. (2001) teaches the routine purification of MHC Class II antigenic peptides comprising the lysing of MHC Class II expressing cells, the isolation of MHC Class II/antigenic peptide complexes, and the subsequent purification of the peptides from said complexes (see particularly, page 6721, *Purification of naturally produced HLA class II molecules and Pool Sequencing*).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to provide a complex of the peptide comprising the amino acid sequence of SEQ ID NO:49 further comprising an MHC Class II molecule for the identification and study of the peptide and its possible role in the pathogenesis of RA given the teachings of Jüsten et al., that "it is striking" that GILT colocalizes in APCs with intracellular MHC Class II molecules, employing the routine method of Godkins et al. The ordinarily skilled artisan would have been interested in the peptide of SEQ ID NO:49 as a candidate MHC class II antigenic peptide particularly in light of the teachings of Jüsten et al.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ram Shukla, can be reached on (571) 272-0841.

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10. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.

/G.R. Ewoldt/
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